IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ELI LILLY AND COMPANY, **Plaintiff** **v.** **ACTAVIS ELIZABETH LLC, GLENMARK PHARMACEUTICALS INC., USA, SUN PHARMACEUTICAL INDUSTRIES LIMITED, SANDOZ, INC., MYLAN PHARMACEUTICALS INC., APOTEX INC., AUROBINDO PHARMA LTD., TEVA PHARMACEUTICALS USA, INC., SYNTHON LABORATORIES, INC., ZYDUS PHARMACEUTICALS, USA INC.,** **Defendants.**	**REDACTED PUBLIC VERSION** **Civil Action No. 07-3770 (DMC) (MF)**

DEFENDANT MYLAN PHARMACEUTICALS INC.'S RESPONSE TO PLAINTIFF'S COMBINED COUNTERSTATEMENT TO DEFENDANTS' LOCAL RULE 56.1 STATEMENTS IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT

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Pursuant to Local Civil Rule 56.1, Defendant Mylan Pharmaceuticals Inc. ("Mylan") respectfully submits the following response to Plaintiff Eli Lilly and Company's ("Lilly") Combined Counterstatement to Defendants' Local Rule 56.1 Statements in Support of Their Motion for Summary Judgment of Non-Infringement. Mylan's response is submitted in support of its Motion for Summary Judgment of Non-Infringement. To the extent not expressly accepted or undisputed, Mylan disputes Lilly's alleged uncontested facts.

Lilly's Alleged Undisputed Fact	**Mylan's Response**
1. Lilly's U.S. Patent No. 5,658,590 ("'590 patent") is entitled "Treatment of Attention-Deficit/Hyperactivity Disorder" and claims various methods of treating ADHD by administering to a patient an effective amount of atomoxetine hydrochloride. (*See* Pliszka, Ex. B, U.S. Patent No. 5,658,590 (filed Jan. 11, 1995).)	Undisputed.
2. Claim 1 recites: "A method of treating attention-deficit/hyperactivity disorder comprising administering to a patient in need of such treatment an effective amount of tomoxetine." (*See* Pliszka, Ex. B, '590 patent at claim 1, col. 4, ll. 24-26.) Claims 2-16 depend from Claim 1 and recite more particular methods of treating ADHD by, for example, referring to a specific patient population (adult, child, or adolescent) (*see id.* claims 2-4, col. 4, ll. 27-34) or subtype of ADHD (predominantly inattentive type, predominantly hyperactive-impulsive type, or combined type) (*see id.* claims 5-16, col. 4, ll. 35-62.)	Undisputed.
3. Lilly invented, researched, developed, and now markets STRATTERA® brand atomoxetine capsules, approved by the FDA for only one indication: the treatment of ADHD. (*See* Chuderewicz, Ex. 3, Prescribing Information for Strattera® Capsules at § 1.1; *see also* Chuderewicz, Ex. 4, FDA Approval Letter for Strattera® Capsules, Nov. 26, 2002.)	Mylan does not dispute that Strattera® has been approved by the FDA for the treatment of ADHD; however, Mylan disputes the remainder of this alleged fact because Mylan lacks sufficient knowledge or information to respond.
4. The claims of the '590 patent cover the only FDA-approved use of Strattera® (for treating ADHD), and as required by 21 U.S.C. § 355(b)(1), Lilly submitted information concerning the '590 patent to the FDA in	Undisputed.

connection with its New Drug Application, NDA No. 21-411 for Strattera®. The FDA thereafter included information concerning the '590 patent in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") in connection with NDA 21-411 for Strattera®. (*See* Doc. No. 3, First Am. Compl. ¶¶ 26-27.)	
5. The claims of the '590 patent require "administering" atomoxetine to a patient in need of treatment of ADHD. (*See* Pliszka, Ex. B, '590 patent at col. 4, ll. 24-62.)	Undisputed.
6. This Court, as well as Defendant Sun Pharmaceutical Industries, Ltd. ("Sun"), has recognized that the "administration" step is the central limitation in the claims of the '590 patent. (*See, e.g.*, Chuderewicz, Ex. 5, Opinion Granting Mot. For Partial Summ. J. of No Direct Infringement (Dkt. No. 331) at 6, May 20, 2009; Sun Br. Summ. J. 15.)	Disputed. In its Opinion, the Court did not state that the "administering" step of claim 1 of the 590 patent is the "central limitation." (Dkt. No. 331) Indeed, **REDACTED** every method claim of the '590 patent has at least two process step limitations: (i) "*treating*" a patient with ADHD, and (ii) "*administering*" atomoxetine to that patient. (*See, e.g.*, Mylan's Reply,[1] Section I(B)). **REDACTED**
7. **REDACTED** and Mylan Pharmaceuticals, Inc. ("Mylan") acknowledge that patients or the patients' parents are the entities who will "administer" the atomoxetine. **REDACTED** Mylan Br. Summ. J. 7.)	Mylan does not dispute that the word "administer" refers to the patient administering atomoxetine to himself or herself, or the patient's parent administering atomoxetine to the patient.
REDACTED	Undisputed.

[1] "Mylan's Reply" refers to Mylan's Reply Brief in support of its Summary Judgment Motion for Non-Infringement, which is being submitted concurrently herewith.

9. Defendants' ANDA submissions and proposed labels alone establish that direct infringement will occur. (*See*, **REDACTED**	Disputed. **REDACTED**
REDACTED	**REDACTED**
11. Lilly's expert, Dr. E. M. Kolassa, was not tasked with proving direct infringement. Rather, his opinions are limited to refuting the propriety of Defendants' use of NDTI data. **REDACTED**	It is undisputed that Lilly, through Dr. Kolassa, was granted leave to serve a reply expert report "solely limited to addressing IMS data in the context of secondary considerations." (Dkt. No. 282). However, to the extent Lilly is implying that Dr. Kolassa's statements cannot be used when considering infringement, Mylan disputes any such implication.
12. Defendants have taken "active steps" to induce another to infringe. On May 29, 2007 – in the fourth	Disputed. While Mylan does not dispute that it submitted its ANDA

[2] "Mylan's Motion" refers to Mylan's Motion for Summary Judgment of Non-Infringement (Dkt. No. 308).
[3] "Mylan's Opposition" refers to Mylan's Opposition to Lilly's Motion for Summary Judgment of Infringement (Dkt. No. 376).
[4] "Boghigian Dec." refers to the Declaration of Harry Boghigian attached as Exhibit H to the Certification of Brian J. Robinson in support of Teva's opposition to Lilly's motion for summary judgment of infringement and cross-motion for summary judgment of non-infringement (Dkt. No. 381).

year after the approval and launch of Strattera® and on the first day permitted under the Hatch-Waxman Act – Defendants submitted ANDAs for generic atomoxetine with the FDA. **REDACTED** Defendants' ANDAs all seek approval for the treatment of ADHD, including each of the subtypes and patient populations claimed in the '590 patent claims. **REDACTED**	for generic atomoxetine which seeks approval for the treatment of ADHD, Mylan disputes that the filing of its ANDA constitutes "active steps" to induce another to infringe. **REDACTED**

REDACTED

REDACTED	
REDACTED	Undisputed.
REDACTED	

[5] "SOF" refers to Mylan's Local 56.1 Statement of Undisputed Material Facts in Support of its Motion for Summary Judgment of Non-Infringement (Dkt. No. 308-2).

REDACTED

REDACTED	Disputed. **REDACTED**
REDACTED	This alleged fact involves issues solely related to a defendant other than Mylan. Mylan objects to this alleged fact because it is completely irrelevant to Mylan's motion for summary judgment and is therefore not a material fact with respect to that motion. Accordingly, Mylan has no obligation to respond to this fact. To the extent a response is required,

	Mylan disputes this alleged fact.
	This alleged fact involves issues solely related to a defendant other than Mylan. Mylan objects to this alleged fact because it is completely irrelevant to Mylan's motion for summary judgment and is therefore not a material fact with respect to that motion. Accordingly, Mylan has no obligation to respond to this fact. To the extent a response is required, Mylan disputes this alleged fact.
REDACTED	Disputed. Mylan's proposed ANDA product is indicated for ADHD. (Shanley Dep. 101:10-17, 14:5-22, 21:9-18; 54:11 – 55:15, 126:5-13, Nov. 6, 2008.) Further, Mylan's corporate witness confirmed that, with respect to the product insert, "Mylan has no intentions on this document. [Mylan] just include[s] it on the ANDA because the FDA requires it." (Jhun Dec., Ex. E: Shanley Dep. Tr. 126:2-4). Mylan disputes the remainder of this alleged fact.
	This alleged fact involves issues solely related to a defendant other than Mylan. Mylan objects to this alleged fact because it is completely irrelevant to Mylan's motion for summary judgment and is therefore not a material fact with respect to that motion. Accordingly, Mylan has no obligation to respond to this fact. To the extent a response is required, Mylan disputes this alleged fact.
	This alleged fact involves issues solely related to a defendant other than Mylan. Mylan objects to this alleged fact because it is completely

	irrelevant to Mylan's motion for summary judgment and is therefore not a material fact with respect to that motion. Accordingly, Mylan has no obligation to respond to this fact. To the extent a response is required, Mylan disputes this alleged fact.
REDACTED	This alleged fact involves issues solely related to a defendant other than Mylan. Mylan objects to this alleged fact because it is completely irrelevant to Mylan's motion for summary judgment and is therefore not a material fact with respect to that motion. Accordingly, Mylan has no obligation to respond to this fact. To the extent a response is required, Mylan disputes this alleged fact. Mylan has consistently maintained that the manufacture, use, and/or sale of its proposed ANDA products would not infringe the claims of the '590 patent. (*See, e.g.*, Dkt. No. 173, Mylan's Second Am. Answer).
	This alleged fact involves issues solely related to a defendant other than Mylan. Mylan objects to this alleged fact because it is completely irrelevant to Mylan's motion for summary judgment and is therefore not a material fact with respect to that motion. Accordingly, Mylan has no obligation to respond to this fact. To the extent a response is required, Mylan disputes this alleged fact. Mylan has consistently maintained that the manufacture, use, and/or sale of its proposed ANDA products would not infringe the claims of the '590 patent. (*See, e.g.*, Dkt. No. 173, Mylan's Second Am. Answer).

REDACTED	This alleged fact involves issues solely related to a defendant other than Mylan. Mylan objects to this alleged fact because it is completely irrelevant to Mylan's motion for summary judgment and is therefore not a material fact with respect to that motion. Accordingly, Mylan has no obligation to respond to this fact. To the extent a response is required, Mylan disputes this alleged fact. Mylan has consistently maintained that the manufacture, use, and/or sale of its proposed ANDA products would not infringe the claims of the '590 patent. (*See, e.g.*, Dkt. No. 173, Mylan's Second Am. Answer).
	This alleged fact involves issues solely related to a defendant other than Mylan. Mylan objects to this alleged fact because it is completely irrelevant to Mylan's motion for summary judgment and is therefore not a material fact with respect to that motion. Accordingly, Mylan has no obligation to respond to this fact. To the extent a response is required, Mylan disputes this alleged fact. Mylan has consistently maintained that the manufacture, use, and/or sale of its proposed ANDA products would not infringe the claims of the '590 patent. (*See, e.g.*, Dkt. No. 173, Mylan's Second Am. Answer).
27. Other Defendants (*i.e.*, Apotex, Inc. ("Apotex") and Teva Pharmaceuticals USA, Inc. ("Teva")) notably have not moved for summary judgment of non-infringement. This suggests that they concede there is at least a genuine issue of material fact as to whether their uses of generic atomoxetine products infringe the method claims of the '590 patent.	Disputed. Defendants Apotex and Teva filed cross-motions for Summary Judgment of Non-Infringement on July 8, 2009. (*See* Dkt. Nos. 394, and 380, respectively).

REDACTED	**REDACTED**
REDACTED	This alleged fact involves issues solely related to a defendant other than Mylan. Mylan objects to this alleged fact because it is completely irrelevant to Mylan's motion for summary judgment and is therefore not a material fact with respect to that motion. Accordingly, Mylan has no obligation to respond to this fact. To the extent a response is required, Mylan disputes this alleged fact.
	This alleged fact involves issues solely related to a defendant other than Mylan. Mylan objects to this alleged fact because it is completely irrelevant to Mylan's motion for summary judgment and is therefore not a material fact with respect to that motion. Accordingly, Mylan has no obligation to respond to this fact. To the extent a response is required, Mylan disputes this alleged fact.
	This alleged fact involves issues solely related to a defendant other than Mylan. Mylan objects to this alleged fact because it is completely irrelevant to Mylan's motion for summary judgment and is therefore

REDACTED	not a material fact with respect to that motion. Accordingly, Mylan has no obligation to respond to this fact. To the extent a response is required, Mylan disputes this alleged fact.
	A portion of this alleged fact involves issues solely related to a defendant other than Mylan. Mylan objects to this alleged fact because it is completely irrelevant to Mylan's motion for summary judgment and is therefore not a material fact with respect to that motion. Accordingly, Mylan has no obligation to respond to this fact. To the extent a response is required, Mylan disputes this alleged fact as it pertains to Apotex. **REDACTED**
REDACTED	Disputed. **REDACTED**

	REDACTED
REDACTED	Disputed. **REDACTED**
	This alleged fact involves issues solely related to a defendant other than Mylan. Mylan objects to this alleged fact because it is completely irrelevant to Mylan's motion for summary judgment and is therefore not a material fact with respect to that motion. Accordingly, Mylan has no obligation to respond to this fact. To the extent a response is required, Mylan disputes this alleged fact.
	This alleged fact involves issues solely related to a defendant other than Mylan. Mylan objects to this

	alleged fact because it is completely irrelevant to Mylan's motion for summary judgment and is therefore not a material fact with respect to that motion. Accordingly, Mylan has no obligation to respond to this fact. To the extent a response is required, Mylan disputes this alleged fact.
REDACTED	This alleged fact involves issues solely related to a defendant other than Mylan. Mylan objects to this alleged fact because it is completely irrelevant to Mylan's motion for summary judgment and is therefore not a material fact with respect to that motion. Accordingly, Mylan has no obligation to respond to this fact. To the extent a response is required, Mylan disputes this alleged fact.
	REDACTED

REDACTED	
	REDACTED
	This alleged fact involves issues solely related to a defendant other than Mylan. Mylan objects to this alleged fact because it is completely irrelevant to Mylan's motion for summary judgment and is therefore not a material fact with respect to that motion. Accordingly, Mylan has no obligation to respond to this fact. To the extent a response is required, Mylan disputes this alleged fact.
	REDACTED

REDACTED	REDACTED

REDACTED

[6] "Staller Report" refers to Exhibit A to the Declaration of Jud A. Staller, M.D. in Support of Defendant Aurobindo Pharma Ltd.'s Motion for Summary Judgment of Non-Infringement (Dkt. No. 288).

[7] "Boghigian Report" refers to Exhibit A to the Declaration of Harry C. Boghigian in Support of Defendant Aurobindo Pharma Ltd.'s Motion for Summary Judgment of Non-Infringement (Dkt. No. 287).

REDACTED	**REDACTED**
	This alleged fact involves issues solely related to a defendant other than Mylan. Mylan objects to this alleged fact because it is completely irrelevant to Mylan's motion for summary judgment and is therefore not a material fact with respect to that motion. Accordingly, Mylan has no obligation to respond to this fact. To the extent a response is required, Mylan disputes this alleged fact.
	REDACTED
	Disputed. **REDACTED**

REDACTED

REDACTED	This alleged fact involves issues solely related to a defendant other than Mylan. Mylan objects to this alleged fact because it is completely irrelevant to Mylan's motion for summary judgment and is therefore

[8] Sec. Jhun Dec., Ex. __" refers to the Second Certification of Jane Jhun in Support of Mylan's Motion for Summary Judgment of Non-Infringement, which is being submitted concurrently herewith.

[9] "Teva's Opposition" refers to the Memorandum in Support of Defendant Teva's Opposition to Plaintiff's Motion for Summary Judgment of Infringement and in Support of Teva's Cross-Motion for Summary Judgment of Infringement (Dkt. No. 414).

	not a material fact with respect to that motion. Accordingly, Mylan has no obligation to respond to this fact. To the extent a response is required, Mylan disputes this alleged fact.

REDACTED

REDACTED

REDACTED

Mylan also respectfully submits the following additional undisputed facts in support of its Motion for Summary Judgment of Non-Infringement.

59. Patient compliance is a well-known challenge in the world of medicine, especially in the context of treating ADHD. (Second Jhun Dec., Ex. B: Perwien et al., Stimulant Treatment Patterns and Compliance in Children and Adults with Newly Treated Attention-Deficit/Hyperactivity Disorder, *J. Manag Care Pharm.* 2004 Mar-Apr; 10(2):122-9).

Dated: July 27, 2009

Respectfully submitted,

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